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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,834	02/11/2002	David M. Koelle	G&C 30967.3-US-D1	5976

7590 03/08/2004

Attention: Karen S. Canady
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EXAMINER	
MOSHER, MARY	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 03/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/073,834	KOELLE ET AL.	
	Examiner	Art Unit	
	Mary E. Mosher, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,26,27 and 30-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) ____ is/are allowed.

6)☒ Claim(s) *1-17,26,27 and 30-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/19/2002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of invention 3, UI49 polypeptides in Paper No. 12/22/2003 is acknowledged. The traversal is on the ground(s) that the MPEP uses incorrect statutory construction, and all claimed inventions involve a common inventive concept of being an HSV antigen. This is not found persuasive because applicant has not admitted that all HSV antigens are obvious variants of a single invention, and because the examiner lacks authority to countermand the MPEP. However, after search of UL49, the examiner has determined that it would not be unduly burdensome to jointly examine this polypeptide and the corresponding nucleic acid. Therefore all of the claims have been examined, but only to the extent that they read upon UL49 polypeptides and coding sequences.

The requirement is still deemed proper and is therefore made FINAL.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-17, 26, 27, 30-54 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-32 of copending Application No. 10/210428. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims include the same UL49 products and methods.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

Claims 7-11, 13, 15, and 33 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 7 is indefinite because it uses both open and closed language for the same amino acid sequence: "comprising an amino acid sequence consisting essentially of..." Which scope is intended, "consisting essentially of" or "comprising"? This affects the dependent claims. For the purposes of this office action, these claims will be treated as "comprising the sequence," since this is the broadest reasonable interpretation.

Claims 26 and 27 re rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for inducing an immune response against HSV, does not reasonably provide enablement for a method of preventing HSV infection. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The specification teaches that UL49 and

specified fragments are useful for inducing various types of immune response. However, the specification fails to provide evidence that the induced immune response is able to prevent infection. Since effective immunoprophylaxis of HSV infection (and other sexually transmitted diseases) is not routine in the art, one skilled in the art would have reason to doubt an unsupported assertion regarding prevention of infection. Considering the state of the art, the limited teachings of the specification, the absence of a working example, and the unpredictability of a protective immune response, it is concluded that undue experimentation would be required to practise the full scope of the invention as claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-17, 30-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Burke et al US 6,635,258. Burke teaches a pharmaceutical composition comprising HSV VP22, which is the same as HSV UL49, with pharmaceutical carrier and adjuvant, see claims 1-3. In addition, Burke teaches immunogenic polynucleotides, recombinant viruses, and purification of fusion proteins, see e.g. columns 16, 20-22, 35-41. Therefore the patent clearly meets the limitations for claims 1-17, 30-34, 39-42. In

addition, although the patent does not explicitly discuss enhancing proliferation of HSV-specific T cells or enhancing the production of HSV-specific antibodies, these would be the inherent outcome of the immunize/boost protocol used in Example 2, Table 11. Therefore, the patent meets the limitations of claims 35-38 as well.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burke et al US 6,635,258. These claims are drawn to a method of treating or preventing an HSV infection in a subject. Burke explicitly suggests using the disclosed compositions to treat or prevent an HSV infection. Since Burke shows that immunized animals develop a CTL response, there is a reasonable expectation of success at least

for treating an infection in a subject. Therefore, the invention as a whole is prima facie obvious, absent unexpected results.

Allowable Subject Matter

Claims 43-54 would be allowable if limited to the elected UL49 product, subject to resolution of provisional double patenting issues.

The following is a statement of reasons for the indication of allowable subject matter: Although the HSV1 and HSV2 UL49 differ somewhat in structure, both are similar in length so that "residues 105-190 or 177-220" are readily recognizable for both species of virus, and even share some similarities in structure within these regions. See NCBI locus CAA32299 and CAB06735 as evidence. Therefore, this recitation is seen as definite, even though it does not specify the HSV species or recite a SEQ ID number. The prior art does not point to residues 105-190 or 177-220 of UL49/VP22. Burke et al US 6,635,258 teaches that the protein has epitopes of interest, but does not teach where those epitopes are located within the primary structure. McLauglan et al US 6,200,577 teaches and claims a peptide which is the same as HSV1 residues 190-220, but does not provide any motivation to add residues 177-189 to the peptide. Other prior art, e.g. O'Hare et al WO 97/05265 page 4, points to C-terminal fragments of the protein for use in protein targeting, but does not point to the regions recited in these claims. Hope et al 6,340,577 teaches a fusion protein with HSV1 UL49 residues 173-275, but does not provide any motivation to reach the recited peptides. Applicant has shown that these regions possess useful immunological properties. Therefore, peptides consisting essentially of residues 205-190 or 177-220 are seen as allowable, as are fusion proteins

that have the peptides fused to a heterologous sequence, as are nucleic acids with similar scope.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

2/27/04

MARY E. MOSHER
PRIMARY EXAMINER
GROUP ~~1800~~ 1600